

ECCO – AACR – EORTC – ESMO

Jointly organise the Flims workshop

METHODS IN CLINICAL CANCER RESEARCH

The 12th intensive workshop for European junior clinical oncologists in any clinical research specialty area, to learn the essentials of clinical trial design

19-25
JUNE
2010

Waldhaus Flims, Switzerland

PROGRAMME COMMITTEE

Workshop Directors

Will P. Steward, Scott M. Lippman, Jan Bogaerts, Lillian L. Siu, Johann de Bono

The core faculty

Fatima Cardoso (BE), Janet E. Dancey (CA), Charles Erlichman (USA), Stephen M. Hahn (USA), Susan G. Hilsenbeck (USA), Peter Hohenberger (DE), Ian Judson (UK), Philippe Lambin (NL), Patricia M. LoRusso (USA), Riccardo Riccardi, (IT), Patrick Schöffski (BE), Sandra M. Swain (USA)

The 12th ECCO-AACR-EORTC-ESMO Workshop is supported by generous grants from national cancer organisations and educational grants from corporate sponsors.



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Representing ASCO

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Representing ESMO

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*“Learn from the experts
how to design an effective
therapeutic clinical trial
in any oncological
research subspecialty”*

WORKSHOP FACULTY

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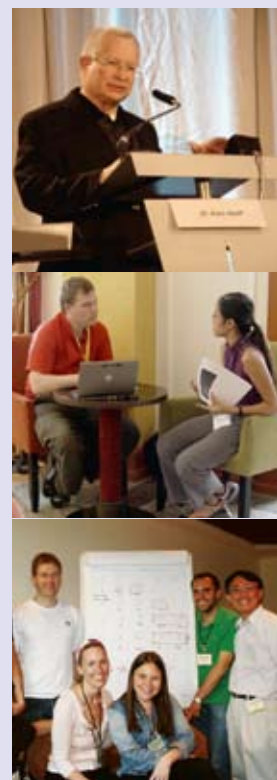
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ECCO, AACR, EORTC and ESMO would like to acknowledge the American Society of Clinical Oncology (ASCO) for their support to the Faculty.

Additional faculty to be announced. Faculty disclosures will be provided in the Workshop syllabus.

GOALS OF THE WORKSHOP

Errors made in the design and conduct of a clinical trial can make it impossible for the trial to provide a definitive answer about the effectiveness of a new approach. Poor design can thus lead to the abandonment of promising avenues of research that are based on sound basic scientific work and to delays in the introduction of new treatments into the general practice of medical oncology. ECCO, AACR, EORTC and ESMO have responded to this problem by designing jointly a programme that will:

- 1** Introduce junior clinical oncologists in any oncology subspecialty to the principles of good clinical design: i.e. give them the tools they need to conduct clinical trials that will yield clear results which investigators can use to proceed to the next level of research;
- 2** Expose junior clinical oncologists to the full spectrum of challenges in clinical research, from conventional antineoplastic agents and multidisciplinary treatment regimens to gene therapy, in the expectation that they will then want to devote all or a portion of their future careers to some aspects of clinical research;
- 3** Develop a cadre of well-trained, experienced researchers whose expertise will foster better clinical trial designs and thereby hasten the introduction of improved regimens for cancer therapy and prevention into everyday medical practice and patient care.

SCIENTIFIC SESSION FORMATS

The scientific programme for the Workshop will consist of four educational formats to serve a variety of didactic needs:

- a Protocol development sessions** during which each participant develops a concept sheet for a clinical trial protocol and, through extensive mentoring, completes the writing of the protocol before the end of the Workshop. These sessions constitute the core activity of the Workshop and allow students to apply the lessons learned in the Workshop to their own programmes and to receive detailed critiques of their proposals from experienced scientists.
- b Small group discussion sessions** on special topics. These sessions focus on topics that are either essential to the success of many different kinds of clinical trials or facilitate discussion on and around the intricacies of a particular type of trial in a small group session. These sessions will be limited in size to maximise exchange of information.
- c Lectures and panel discussions** on specific topics presented by experts in the field. These talks provide participants with an overview of the design and conduct of high-quality clinical trials. Where appropriate, lectures on related topics are followed by a panel discussion or round table session during which faculty and students can explore issues raised during the talks in greater depth.
- d One-on-one sessions** for individual counselling and advice on protocol and career development.

“Well-designed and conducted clinical trials are critical to achieving advances in cancer research and the prompt the introduction of effective new treatment for cancer patients”



PRELIMINARY WORKSHOP PROGRAMME

Participants should arrive in Flims on Saturday 19 June 2010 no later than 04.00 p.m. The Workshop will begin with a mandatory pre-test at 04.00 p.m. There will also be a compulsory post-test on Thursday 24 June 2010. The Workshop will adjourn after breakfast on Friday 25 June 2010.

DAY 1 SATURDAY 19 JUNE 2010

12:00 – 16:00	Registration
16:00 – 17:00	Pre-test (mandatory for all fellows)
17:00 – 17:35	Welcome and Workshop overview
17:35 – 18:15	Introductory lecture: Questions to ask yourself in designing a clinical trial
18:30 – 20:30	Protocol development session 1

DAY 2 SUNDAY 20 JUNE 2010

08:00 – 09:45	Lecture session 1 <ul style="list-style-type: none">• Phase I trials of chemotherapy and targeted drugs• Phase II trials• Randomised phase II trials
10:00 – 12:30	Lecture session 2 <ul style="list-style-type: none">• Phase III trials• Basic biostatistics for the clinical trialist I• Basic biostatistics for the clinical trialist II• Common errors in statistics
13:30 – 15:30	Protocol development session 2
16:00 – 17:00	Small Discussion Groups - session 1
17:15 – 18:15	Small Discussion Groups - session 2
18:15 – 19:30	Individual work on protocols
20:45	Individual work on protocols
20:45 – 22:45	Meet-your-expert session (office hours)
21:30	Protocol concept sheets due - optional

DAY 3 MONDAY 21 JUNE 2010

08:00 – 09:00	Individual work on protocols
09:00	Protocol concept sheets due
09:00 – 10:20	Lecture session 3 <ul style="list-style-type: none">• Special considerations in trials of radiation therapy – implications for design, endpoints and quality control• Special considerations in combined treatment trials (Chemo-radiation) – implications for design, endpoints and quality control
10:35 – 12:00	Lecture session 4 <ul style="list-style-type: none">• Integrating surgery in multi-modality trials – implications for design, endpoints and quality control• Design of studies with immunological aspects
13:00 – 14:00	Lecture – Prognostic and predictive markers for patient selection
14:00 – 16:00	Protocol development session 3
16:00	Free time
20:45	Individual work on protocols

DAY 4 TUESDAY 22 JUNE 2010

07:50 – 10:10	Lecture session 5 <ul style="list-style-type: none">• Role of pharmacokinetics in clinical trials• Clinical trial design for biomarkers• What can imaging contribute to your trial?• Round table: When to incorporate correlative studies? – imaging, laboratory
10:25 – 12:30	Lecture session 6 <ul style="list-style-type: none">• Ethical principles in the conduct of clinical trials• Patient-oriented endpoints / Quality of Life• Round table – Ethical issues and informed consent – a case-based discussion
13:30 – 15:00	Protocol development session 4
15:15 – 17:30	Meet-your-expert session in parallel with Small Discussion Group sessions and individual work on protocols
15:15 – 16:15	Small Discussion Groups - session 3
16:30 – 17:30	Small Discussion Groups - session 4
17:30 – 19:00	Individual work on protocols
20:30 – 21:30	Meet-your-expert session (continued)
21:30	Protocol drafts due - optional

DAY 5 WEDNESDAY 23 JUNE 2010

08:00 – 09:30	Individual work on protocols
09:30	Protocol drafts due
09:30 – 10:30	Lecture session 7 <ul style="list-style-type: none">• How to write a successful grant application• Reading the literature with a critical eye
10:45 – 12:30	Lecture session 8: “Barriers to successful implementation” <ul style="list-style-type: none">• Regulatory and other practical issues• Investigators’ responsibilities – funding and implementation aspects• Hospital management issues and the role of the research nurse• Panel discussion
13:30 – 15:30	Protocol development session 5
15:45 – 19:00	Individual work on protocols
20:15	Individual work on protocols

DAY 6 THURSDAY 24 JUNE 2010

08:30 – 10:30	Lecture session 9 <ul style="list-style-type: none">• Molecular targeting and the prevention-therapy convergence• Data and safety monitoring• Improving patient participation in cancer clinical trials• Discussion
10:50 – 12:30	Protocol development session 6
13:30 – 16:00	Individual work on protocols
16:00 – 17:00	Post-test (mandatory for all fellows)
18:00	Final protocol due
20:00	Reception and dinner

DAY 7 FRIDAY 25 JUNE 2010

Departure

OVERVIEW OF THE SMALL DISCUSSION GROUP SESSIONS

- Basics of clinical trial design
- Practical aspects of correlative studies: focus on laboratory studies
- Randomised trials: techniques, limitations, practical aspects (focus on randomised general and including adaptive designs)
- Software for sample size computation: how do I calculate my phase II protocol?
- Phase I trial endpoints, novel designs
- Practical aspects of correlative studies: focus on imaging studies
- Phase II clinical trials: new designs – new endpoints
- Software for sample size computation: how do I calculate my phase III protocol?
- Radiotherapy trials
- Paediatric clinical trials
- Surgical clinical trials
- Randomised trials: techniques, limitations, practical aspects (focus on randomised phase II)
- Biobanking and set-up of translational research
- Written and oral research presentations that audiences remember

ONLINE APPLICATION PROCEDURE

Applications to participate in the ECCO-AACR-EORTC-ESMO Workshop on Methods in Clinical Cancer Research can only be submitted electronically. Paper submissions will not be accepted.

Visit the Workshop website: www.ecco-org.eu (select 'Education>Flims>Flims 12') and follow the instructions on the screen.

DEADLINE FOR RECEIPT OF APPLICATIONS: FRIDAY 12 FEBRUARY 2010.

All applicants must submit the online application form and upload ONE single document which should include the following four items:

- 1** A one-page description of the clinical therapeutic trial protocol to compile during the Workshop to include:
 - **Title:** Example: "An open label phase II randomised study to compare the efficacy of dasanib (BMS-354825) vs. temozolamide in patients with unresectable AJCC stage 3 or 4 malignant melanoma".
 - **Keywords:** Select at least 2 keywords from the following list which are applicable to your trial protocol: Phase I, Phase II, Phase III, Phase I/II, Phase II/III, drug, surgery, or radiotherapy.
 - **Main objective of the trial:** Describe in 2-3 sentences.
 - **Proposed trial design:** No more than one paragraph describing the elements of the trial. A schematic diagram may be used instead of narrative.
 - **Rationale for performing this trial:** Describe in 2-3 sentences.
 - **Characteristics of the population under study:** Outline 2-3 major points.
 - **Proposed endpoints / measurable outcomes:** Bullet points (primary, secondary).
 - **Feasibility of the study:** Access to the required number of patients, adequate supplies of the drugs and resources.
 - **Translational studies (imaging, laboratory):** What translational studies would you consider? Please specify.
- 2** A CV including a digital photograph (in low resolution).

3

A letter of motivation explaining the reasons for wanting to participate in this Workshop.
The following elements should be included:

- Date when specialty training will be completed (month, year) and a description of previous research background.
- A description of the programme you are scheduled to participate in over the next two years.
- An indication of the type of programme in which you would ideally wish to be working in 5 years time.
- An explanation of how your participation in the Workshop would help the design and conduct of the trial to be outlined the partly final protocol.
- An agreement to participate in the long-term evaluation of this Workshop by maintaining contact with the organisers and responding to questionnaires when requested.
- A guarantee that the submitted study concept will not be developed prior to the Workshop and will not be active by the time the Workshop starts.

4

A statement from the applicant's Supervisor/Head of Department in support of the application, describing his/her commitment to long-term follow-up and facilitation of the implementation of the study designed at the Workshop. Full contact details, including Email address should be included as well as the following points:

- A description of the length of time and the capacity in which the Supervisor/Head of Department has known the applicant.
- An assessment of the quality of the applicant's performance in his/her current programme.
- A commitment to make every reasonable effort to enable the candidate to conduct a clinical trial based on the protocol produced at the Workshop. The Supervisor/Head of Department should confirm the "feasibility" of the proposed trial within the institutional setting
- A commitment to participate in the long-term evaluation of this Workshop by reporting the results of the trial conducted by the candidate to the organisers and by responding to questionnaires that may be submitted by the organisers.
- An assurance that if the initial protocol concept is changed partly or drastically during the Workshop this will be accepted.
- A guarantee that the study concept which has been submitted will not be developed prior to the Workshop and will not be active by the time the Workshop starts.

Please ensure that the uploaded document size does not exceed 4 MB.

Applications will not be accepted unless they contain all four elements described above.

Applicants are strongly encouraged not to wait until the final deadline to submit applications since this may cause system overload.

For any queries or questions concerning application, please contact Kaat Cumps, Flims Workshop Coordinator: Tel: +32(0)2 775 29 33, Email: kaat.cumps@ecco-org.eu

Two other workshops similar to Flims are held in Vail (USA) annually and in Australia in alternate years. The organisers of the Flims, Vail and Australian workshops would like to stress that applications will only be accepted for one workshop.

MINIMUM SELECTION CRITERIA

1. Be a junior physician in at least the 2nd year of training in an oncology specialty and within 5 years of completion of training.
2. Have a major interest in clinical research and intend to develop a career in that field.
3. Aim to write and conduct a clinical protocol for a study not previously performed, nor written, which is also considered feasible within the institutional setting and the time of completion of the candidate's clinical training.
4. Be fluent in written and spoken English and have good computer skills.
5. Have support from the Supervisor/ Head of Department and sustained commitment in the years following the Workshop.

GENERAL INFORMATION

Selection of participants

The Programme Committee will review applications and select 80 participants (physicians). Preference will be given to those who are close to the end of their Residency/Fellowship training and to junior staff, within 5 years of completing their training. The Committee will further base its decisions on the quality and feasibility of the proposed protocol concept and the letters of commitment submitted by both the applicant and the Supervisor/Head of Department.

These documents will be evaluated on the basis of the information they contain about the candidate and the assurances they provide about the participation of both the candidate and his/her Supervisor/Head of Department in the long-term evaluation of the Workshop. The Committee will seek a group of 80 trainees who have made outstanding progress in their medical training, displayed an interest and competence in clinical cancer research, and who will come from a diverse group of European training institutions and personal backgrounds. A maximum of 2 candidates from the same institution can be accepted. Hence, institutions will be asked to prioritise should more than 2 of their fellows obtain high review scores. A limited number of non-European applicants will be accepted.

Important selection criteria:

- Study proposals with a feasible design addressing a sound scientific question/concept, with a clinically relevant primary endpoint and limited secondary endpoints, not studied before.
- Applicants who have the support from relevant departments/institution or groups to help conduct the proposed clinical trial after attending the Workshop.
- At least preliminary commitment obtained from sponsor to provide study agent(s) of interest (if applicable).

The submission of study proposals requiring very large sample sizes and prolonged follow-up to address the primary endpoint is very much discouraged, unless the applicant is able to implement such study within the institutional setting.

For applications from countries with limited resources, the eligibility criteria to implement the newly designed trial upon return from the Workshop to their home institution will be re-evaluated.

Applicants from Eastern European countries are particularly encouraged to apply.

Applicants and their Heads of Department must guarantee that the study concept submitted with the application will not be changed prior to attending the Workshop. In addition, they agree that the submitted study concept will not be developed or active prior to the Workshop. Candidates who disregard this regulation may be requested to forfeit their place on the Workshop. Failure to comply with this rule will also result in an immediate ban of any students from the same institute applying the following year.

Applicants will be notified about their status by early April 2010.

The decision of the Selection Committee is final. An appeal process for unsuccessful candidates will not be available. Due to the large

number of applications received each year, requests for individual feedback cannot be accommodated.

The official language of the Workshop is English and all protocols should be written in English. Basic computer knowledge will be required to develop the protocol on site.

Students will present the concept for the proposed prospective clinical trial at the beginning of the Workshop and leave with a finished protocol.

Participation fee

A participation fee of 2,000 EUR will be imposed on all selected participants to offset part of the actual Workshop costs per student.

The Committee can grant exemptions for up to 20 selected students who are resident in countries with limited resources from paying a participation fee.

Workshop venue and travel

Workshop sessions will take place at Waldhaus Flims, Switzerland. The organisers will arrange complimentary flights between the closest international airport of the participant to home cities and Zurich International Airport. A complimentary shuttle bus service will be available between Zurich Airport and Waldhaus Flims on the morning of Saturday 19 June, and again on Friday 25 June 2010. Workshop participants will receive the schedule of the shuttle buses in advance. Please note that no other complimentary transport between Zurich and Flims will be provided.

Workshop accommodation

All selected participants will receive complimentary hotel accommodation in Flims from 19 June to 25 June inclusive and complimentary meals throughout the Workshop with the exception of dinner on Monday 21 June. Workshop participants are required to stay at Waldhaus Flims for the duration of the Workshop and to participate in all group meals. Fellows will receive complimentary accommodation at the hotel on a shared basis with one other Workshop participant.

Participants requesting single room accommodation will have to pay a supplement of 50 EUR per night/per person.

Workshop materials

All faculty members will contribute material to the Workshop syllabus to be distributed to all participants at the Workshop. For each lecture and small group discussion section the syllabus will contain the instructional objectives of the presentation, an outline of the topics to be covered and a bibliography of relevant articles and texts. Part of the Workshop material will be available on the internet before the Workshop. Onsite, all participants will receive their personal copy of the programme documentation.

Preparation for the Workshop

A background literature review of the relevant tumour type, the therapeutic intervention, as well as on the proposed trial design and its handling would be highly desirable as a preparation for the Workshop and will greatly improve productivity. Participants are also advised to bring this background information to the Workshop, preferably in electronic version, so that it can easily be used in the trial.

In addition, it is considered advantageous that students write a concise (max. 2 pages) trial/disease background document highlighting the focus of their concept in bullet points.



Workshop on

METHODS IN CLINICAL CANCER RESEARCH

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APPLICATION DEADLINE: FRIDAY 12 FEBRUARY 2010 (24:00 CET Brussels time)

www.ecco-org.eu